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Leading article

Towards safer endoscopic retrograde cholangiopancreatography

In the 22 years since its introduction, endoscopic retrograde cholangiopancreatography (ERCP) has become firmly established in the management of biliary and pancreatic disease. It is usually as effective as surgery in treating bile duct stones and involves a shorter hospital stay.[1-3] But is it safer? The answer seems to be a qualified yes. The difficulties in comparing the two modes of treatment have been understood for some time.[1] In particular, patients coming to ERCP tend to be older and in poorer general health than those undergoing surgery.[1-3] With a complication rate of around 7% and a procedure related mortality of 0·6–0·7%,[4 5] however, therapeutic ERCP compares favourably with the morbidity and mortality of surgery for choledocholithiasis.[3]

When patients with malignant obstructive jaundice have been randomised to either surgery or insertion of a large diameter biliary stent, the 30 day mortality in the endoscopic group was significantly lower[6] or showed a trend in that direction.[7] Thus, while the risks of ERCP are relatively fewer, this is not grounds for complacency. Many recent developments provide an opportunity for safer ERCP and endoscopists offering this service should consider incorporating these advances into their practice.

Haemorrhage

Haemorrhage after endoscopic sphincterotomy occurs in 2·5–4% of cases.[4 5] In many of these patients the bleeding stops spontaneously – only 0·4% undergo surgery and 0·2% die.[4 5] Haemorrhage is usually immediate but it can occasionally be a late complication.[8]

It is customary to check patients' blood coagulation before ERCP and correct any detected abnormality. Compatible blood should be available for transfusion before performing a sphincterotomy. Most patients who bleed after this procedure have normal blood clotting, however, indicating that other risk factors are more important than minor coagulation abnormalities.[9]

The most important of these factors is the size of the sphincterotomy.[1 5 10] Large sphincterotomies are usually done in the hope of extracting big stones. Those stones with a diameter of less than 1 cm can almost always be removed, whereas those more than 1·5 cm in diameter often cause difficulties. The shape of the calculus is also a determinant of successful extraction. 'Square' stones are more difficult to remove than more rounded ones. Improved mechanical lithotripters that are often effective[11-13] and reasonably cheap are now available and may reduce the temptation to cut too far when attempting removal of large stones. In one centre, the use of mechanical lithotripsy increased the endoscopic clearance rate of duct stones from 86% to 94%.[13] Nevertheless, failure to grasp very large 'square' calculi still occurs. In patients with this problem who are elderly and in poor general health, other methods of stone fragmentation such as extracorporeal shock wave lithotripsy[14 15] or biliary stenting without stone removal[16-18] may be safer alternatives than either surgery or enlargement of a sphincterotomy that is already a reasonable size. Unless lithotripsy is planned, inserting a stent is preferable to inserting a nasobiliary drain. The latter provides only a temporary solution to the problem, particularly as these drains may be removed by confused elderly patients at night. In contrast, stents provide reasonable long term palliation in most cases.[16-18] It would, however, be preferable to have a bile duct free of stones, and Johnson *et al* recently reported that in such patients initially treated with an endoprosthesis, eight of 10 who had been given ursodeoxycholic acid had cleared their stones within six months compared with only one of 10 not given this bile acid.[19]

Sphincterotomy is sometimes performed to facilitate biliary stenting, and consequent haemorrhage may occasionally be a cause of death.[20] With modern equipment, however, a single, large diameter stent can often be inserted without a sphincterotomy[21 22] and is usually sufficient to provide adequate drainage, even when both lobes of the liver are obstructed by carinoma.[20]

Good sphincterotomy technique is well described in standard texts[23 24] and is crucial to the safety of the procedure. One of the commonest mistakes is attempting to cut with too much wire inside the papilla, partly for fear of losing access to the duct. Sphincterotomes that can be used while a guide wire remains in the common bile duct are now available. The use of this equipment should obviate this problem and also helps to ensure that the sphincterotomy continues in the correct direction. Even with a well performed sphincterotomy of judicious size, unpredictable haemorrhage still occurs in a few cases. The possibility of using endoscopic Doppler ultrasound to detect any large blood vessels lurking in the path of the proposed sphincterotomy has not yet been well evaluated.[25 26]

When bleeding is a steady ooze, it can often be stopped by injections of dilute adrenaline (1 in 10 000). This also facilitates completion of the procedure and thereby drainage of the duct. When blood is spurting this technique is less successful, partly because the endoscopic view may be lost rapidly. Injections should be placed into the apex of the sphincterotomy, avoiding the area around the pancreatic duct. Because uncontrolled spurting haemorrhage is unlikely to stop spon-

taneously and carries a high mortality, patients with this problem, whatever their age and state of health, should be considered for urgent surgical intervention.

Infection

Cholangitis and septicaemia are, in some cases, potentially avoidable complications of ERCP. The most common causes of infection are either the use of endoscopic equipment contaminated with nosocomial pathogens or spread of host derived bacteria after instrumentation of an obstructed biliary tree. *Pseudomonas aeruginosa* is the most frequent contaminant of endoscopes. Septic complications after the introduction of *P aeruginosa* at ERCP are well described[6 27-30] and may occur even in patients who do not have biliary or pancreatic disease.[31 32] Duodenoscopes are more difficult to clean thoroughly than gastroscopes because of the bridging elevator channel and, as they are often used less frequently, their incomplete disinfection or drying allows a greater time for organisms to proliferate.[29] In addition to rigorous mechanical cleansing and effective disinfection of the endoscope, prevention of Pseudomonas infections requires thorough drying before the endoscope is stored and repeat disinfection immediately before its subsequent use to remove any organisms that may have grown.[33 34] It must also be remembered that the cleaning equipment itself, including washing machines, is a potential source of contamination.[29 34] Any water in these cleaning accessories should be changed frequently. All the equipment should be subject to regular microbiological surveillance.

Cannulation and contrast injection of an occluded, and often already infected, bile duct may precipitate overt cholangitis or septicaemia. Prophylactic antibiotics are therefore advisable in those patients found to have biliary obstruction and mandatory in those in whom the duct has not been cleared. Piperacillin or mezlocillin have been recommended,[35] but many patients now harbour bacteria resistant to these antibiotics.[36 37] Ciprofloxacin or cefotaxime,[36-38] together with metronidazole to cover anaerobic organisms[39] may now be preferable alternatives. In patients at risk of infectious endocarditis, ampicillin usually provides satisfactory prophylaxis.[40 41]

Antibiotics penetrate very poorly into obstructed bile[42] and drainage of the duct is of paramount importance in both relieving and preventing infective complications.[30] It is, therefore, undesirable to undertake ERCP solely as a diagnostic test in jaundiced patients when the endoscopist lacks either the experience or the equipment to relieve the obstructing lesion.

Guide wire exchange and needle-knife papillotomy

New procedures and equipment can facilitate therapeutic ERCP. The guide wire exchange technique can be useful in maintaining access to the common bile duct when the diagnostic cannulation has proved difficult, thereby aiding a successful sphincterotomy or stent insertion. Guide wire technology is continually improving. Newer models have the advantages of increased flexibility and torque control.[43] They may also be easier to negotiate through strictures because of a hydrophilic coating which becomes slippery when wet.[44]

In experienced hands, needle-knife papillotomy can be effective in gaining access to an occluded biliary tree.[45-47] If, despite this procedure, cannulation subsequently fails, a repeat attempt at cannulation will often be successful a few days later when the oedema has subsided. Needle-knife papillotomy is probably a safer option than pre-cutting with a sphincterotome where the wire emerges from the end, as the direction of the cut is easier to control with the needle-knife and there is less danger of damage to the pancreatic duct. Similarly, needle-knife papillotomy may be less hazardous than the alternative method of achieving biliary access using the combined percutaneous-endoscopic procedure.[48 49]

Biliary stenting

Most patients with malignant biliary obstruction in whom a large diameter (10 or 11·5 FG) plastic stent is inserted, die from their tumour while their first stent is still patent.[6] In the remainder, the stents eventually block with a sludge derived from protein, food fibres, bilirubin, and bacteria.[50] Cholangitis then commonly follows. While larger diameter stents remain patent longer than smaller diameter ones,[51 52] many are blocked five to six months after insertion.[51] Attempts to delay stent clogging by prescribing long term antibiotics or by the mucolytic action of aspirin have met with little success,[53] though recent studies suggest that silver impregnation of the stent[54] and omitting side holes[55] may be helpful.

Failure to exchange an occluded stent leaves the patient at risk of infection and often requires the replacement of the stent by the combined percutaneous-endoscopic procedure with its additional hazards.[48 49] This can sometimes be avoided by the use of a newly developed stent exchanger.[56] Employing a short biliary balloon to remove the old stent while leaving a guide wire in place is an alternative technique.[57]

The new metal stents (Wallstent) have been proposed as a possible answer to stent clogging.[58] As they expand to a much greater diameter (24 FG) than plastic stents, they are not subject to occlusion by debris and bacteria, though some become blocked by tumour ingrowth between the stent mesh.[59] A preliminary report suggests that they remain patent longer than plastic stents, produce a more rapid decrease in the patients' jaundice, and are associated with a lower incidence of early cholangitis.[60] Metal stents, however, are expensive, non-removable, and have a short effective length of 6·5 cm.

Acute pancreatitis

Increased serum pancreatic enzyme activities are common after ERCP, but clinically significant pancreatitis occurs in only about 2% of procedures.[4] It is well known that filling of the acina of the gland should be avoided.[61] This may still happen, however, as an inexperienced endoscopist, having achieved a pancreatogram, struggles with the usually more difficult task of obtaining a cholangiogram, making further injections into the pancreatic duct during his attempts.

The newer, non-ionic contrast materials may be less likely to excite pancreatic inflammation than ionic media.[62 63] Even when no contrast has been injected into the gland, pancreatitis may occasionally occur, perhaps as a consequence of manipulation of the ampulla.

Perforation

Perforation, which is usually retroperitoneal, complicates approximately 1% of endoscopic sphincterotomies.[4] An incidence as high as 10% has been reported after combined procedures.[48] Perforation is more likely when cutting non-dilated bile ducts,[64] if the sphincterotomy is large or strays from the line of the duct. A recent study describes 11 patients who had retroperitoneal perforation during ERCP and who were all successfully treated by conservative means.[65] However, this plan of management is advisable only if biliary drainage has been established.

Basket impaction

If basket impaction is to be avoided, it is essential to assess the

size of the sphincterotomy and the lower common bile duct with a balloon catheter, and to compare the size of the balloon with the stone(s) to be removed. The basket should not be closed too tightly as many duct stones are soft and the basket wires may become embedded in the stone so that it cannot be released.

More effective forms of lithotripsy offer the prospect of a reduction in the present rate of basket impaction of 0·2%,[4] and can also be useful in resolving the problem when it arises.[66] Sometimes an impacted basket can be delivered the next day, when the ampullary oedema subsides. Whatever plan of management is adopted, however, it is important that some form of biliary drainage is instituted urgently to lessen the risk of cholangitis.

Hypoxia

The recent British Society of Gastroenterology report on endoscopic safety and monitoring[67] contains much that is germane to the practice of ERCP. Hypoxia is more likely in patients undergoing ERCP than gastroscopy as they are more often elderly and given heavier sedation. In addition, the procedure usually takes longer and an endoscope of a greater diameter is used when biliary stenting is performed.[68]

In most ERCP patients, hypoxia can be avoided by intranasal oxygen given at a rate of 4–5 litres per minute.[69] Nevertheless, Griffin *et al* found in 10% of their patients that oxygen saturation dropped below 90% for longer than a minute even when supplementary oxygen was used and only modest doses of sedative had been given.[69] As careful clinical monitoring is more difficult in the darkened environment in which ERCP is usually performed, this finding illustrates the value of additional patient monitoring by pulse oximetry.

Patient selection

Despite attempts to improve the safety of ERCP, some risk will inevitably remain. It is therefore important to select appropriately those patients who need this investigation, and to balance carefully the risks and expected benefits of any therapeutic procedure. These considerations are especially pertinent with the advent of laparoscopic cholecystectomy. The bile ducts are not often visualised or explored during this operation[70] and it is uncertain how those patients with both duct and gall bladder stones can be identified, either beforehand or perioperatively. Choledocholithiasis is highly unlikely when a technically satisfactory ultrasound indicates a non-dilated duct system that is free of stones,[71 72] particularly when the patient's liver function tests are also normal.[72] If pre-operative ERCP is planned, it can reasonably be reserved for those patients who do not fulfil these criteria.

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